# CLIA - PRE-INSPECTION
# CHECK LIST

The following list of required laboratory practices and documents is an overview of what the on-site survey inspection may consist off; however, please know that additional documents may be required by the surveyor. Use this list only as a guide to prepare your laboratory. Documentation should be organized and available before the scheduled arrival of the inspector. The better organized you are, the easier your inspection will be.

| ADMINISTRATION | Yes | No | N/A |
|---|---|---|---|
| **Inspection Package Instructions Reviewed?** | ☐ | ☐ | ☐ |
| **Laboratory - Declaration of Ownership Completed?** | ☐ | ☐ | ☐ |
| **Laboratory Personnel (CLIA) CMS-Form 209 Completed?** | ☐ | ☐ | ☐ |
| **CMS-116Application – Section VIII (Past Year) Annual Test Volume per specialty completed?** | ☐ | ☐ | ☐ |
| **CMS-116Application - All areas completed and Signed by the Lab Director?** | ☐ | ☐ | ☐ |
| **Previous CLIA Inspection reviewed?** | ☐ | ☐ | ☐ |
| **LABORATORY PERSONNEL** | **Yes** | **No** | **N/A** |
| **All non-waived laboratory personnel listed in CMS Form 209?** | ☐ | ☐ | ☐ |
| **Lab Director qualifying documents on file?** | ☐ | ☐ | ☐ |
| **Moderate Complexity lab-Technical Consultant & Clinical Consultant documents, on file?** | ☐ | ☐ | ☐ |
| **High Complexity lab- Clinical Consultant, Technical Supervisor & General Sup on file?** | ☐ | ☐ | ☐ |
| **Testing personnel qualifying academics on file (GED, High School, AA, BS, MS, PhD, MD, etc)?** | ☐ | ☐ | ☐ |
| **Testing Personnel Job Description and Test Authorization on file?** | ☐ | ☐ | ☐ |
| **Testing personnel Training records on file?** | ☐ | ☐ | ☐ |
| **New Testing personnel Semi-annual (twice-first year) Competency assessments on file?** | ☐ | ☐ | ☐ |
| **Testing personnel yearly Competency assessments on file?** | ☐ | ☐ | ☐ |
| **LABORATORY WRITTEN POLICIES PROCEDURES AND RECORDS** | **Yes** | **No** | **N/A** |
| **List of laboratory test performed available?** | ☐ | ☐ | ☐ |
| **Laboratory Policies and Test procedure manuals available?** | ☐ | ☐ | ☐ |
| **Equipment Manufacturer manuals available?** | ☐ | ☐ | ☐ |
| **Manufacturer kits or reagent inserts available?** | ☐ | ☐ | ☐ |
| **Laboratory Safety Manual available?** | ☐ | ☐ | ☐ |
| **QUALITY ASSESSMENT/QUALITY ASSURANCE** | **Yes** | **No** | **N/A** |
| **Quality Assurance manual available?** | ☐ | ☐ | ☐ |
| **Quality Assurance plan monitored and corrective actions documented?** | ☐ | ☐ | ☐ |
| **PROFICIENCY TESTING (PT) RECORDS** | **Yes** | **No** | **N/A** |
| **Laboratory is enrolled in a PT program for every test or analyte it performs patient testing?** | ☐ | ☐ | ☐ |
| **For tests challenges not available from a PT program, and considered non-regulated. Does the laboratory verify the accuracy of its test results twice annually (split-specimens challenges)?** | ☐ | ☐ | ☐ |
| **PT test results or Evaluation of split-specimens report reviewed and signed by laboratory director or designee?** | ☐ | ☐ | ☐ |
| **Investigation and Corrective actions Documented for unsuccessful PT performances?** | ☐ | ☐ | ☐ |

| PROFICIENCY TESTING (PT) RECORDS (Conti-) | Yes | No | N/A |
|---|---|---|---|
| Documented Review of PT results against the PT provider participant's summary results, for non-graded, non-consensus or artificially assigned scores on file? | ☐ | ☐ | ☐ |
| Documented review of PT minimum passing scores of 80% on file? | ☐ | ☐ | ☐ |
| Review of patient test results to ensure that no tests results were affected during the failed PT? | ☐ | ☐ | ☐ |
| Documented records of all testing personnel participating in PT events? | ☐ | ☐ | ☐ |
| **LABORATORY SYSTEMS CALIBRATIONS AND VERIFICATIONS** | **Yes** | **No** | **N/A** |
| Calibration policies available? | ☐ | ☐ | ☐ |
| System Calibration records (bi-annual, once every 6 months) or more frequently if required? | ☐ | ☐ | ☐ |
| Comparison of Test Results available when performing the same test using different methodology or Instruments? (bi-annual, every 6 months) | ☐ | ☐ | ☐ |
| New equipment Installation (correlation verification studies) available? | ☐ | ☐ | ☐ |
| Performance Specifications for Mod- FDA system or in-house developed methods available? | ☐ | ☐ | ☐ |
| **LABORATORY QUALITY CONTROLS** | **Yes** | **No** | **N/A** |
| Quality Control records for the past two years (logs, instrument print outs or LIS) available? | ☐ | ☐ | ☐ |
| Levey-Jennings charts including other assay ranges available? | ☐ | ☐ | ☐ |
| Documented QC reviews by lab director or designee available? | ☐ | ☐ | ☐ |
| Documented investigations and corrective actions for any QC failures available? | ☐ | ☐ | ☐ |
| **TESTING RECORDS** | **Yes** | **No** | **N/A** |
| Patients test requisitions, accession logs, instrument print outs, or LIS test records available? | ☐ | ☐ | ☐ |
| Logs reviewed? | ☐ | ☐ | ☐ |
| Normal and Panic test values available? | ☐ | ☐ | ☐ |
| Reference Laboratory log available? | ☐ | ☐ | ☐ |
| **LABORATORY MAINTENANCE RECORDS** | **Yes** | **No** | **N/A** |
| Laboratory equipment and systems maintenance logs available? | ☐ | ☐ | ☐ |
| Lab equipment (centrifuges, pipettes, thermometer, timers, hoods, etc) calib/verif available? | ☐ | ☐ | ☐ |
| All Equipment Repairs documented? | ☐ | ☐ | ☐ |
| Test systems repairs or replacement of parts include documented Calibration Verifications? | ☐ | ☐ | ☐ |
| **TEMPERATURE CONTROLLED SPACES, EQUIPMENT AND INSTRUMENTS** | **Yes** | **No** | **N/A** |
| Equipment/Instruments monitored for acceptable temperature ranges? | ☐ | ☐ | ☐ |
| Facility space, temperature and humidity logs available? | ☐ | ☐ | ☐ |
| **LABORATORY TESTING - AREA, SUPPLIES AND SAFETY** | **Yes** | **No** | **N/A** |
| Reagents monitored for date received, open and expiration dates? | ☐ | ☐ | ☐ |
| Expired reagents and test accessories (kits, collect tubes, etc) discarded? | ☐ | ☐ | ☐ |
| Laboratory safety equipment, biohazard waste containers and labels in place? | ☐ | ☐ | ☐ |
| Laboratory with adequate space, good ventilation and clean? | ☐ | ☐ | ☐ |

Self Evaluation Conducted by: _____ Date: _____